



UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/413,785 10/07/99 MANOLAGAS

S D6156

SHERRY M. KNOWLES, ESQ  
KNG & SPALDING  
191 PEACHTREE STREET  
ATLANTA GA 30303-1763

HM22/0605

EXAMINER

BAKER, A

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/413,785	Applicant(s) MANOLAGAS ET AL.	
	Examiner Anne M. Baker	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extension of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any extension of time adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on 22 March 2001.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-5, 15, 16 and 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1-5, 15, 16 and 20-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Applicable Papers

- 9) ☐ Specification is objected to by the Examiner.
- 10) ☐ Drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ Proposed drawing correction filed on 10-7-99 is: a) ☐ approved b) ☒ disapproved.
- 12) ☐ Oath or declaration is objected to by the Examiner.

#### Priorities under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- ☐ b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- ☐ See attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachments

- 15) ☐ References Cited (PTO-892)
- 16) ☐ Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

Application/Control Number: 09/413,785

Page 2

Art Unit: 1632

### **DETAILED ACTION**

The amendment filed March 22, 2001 (Paper No. 9) has been entered. Claim 1 has been amended. Claims 6-14 and 17-19 have been cancelled. Claim 24 has been newly added.

The following rejections are reiterated or newly applied and constitute the complete set of rejections being applied to the instant application. Rejections and objections not reiterated from the previous office action are hereby withdrawn.

#### ***Claim Objections***

Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 recites the limitation "wherein the parathyroid hormone is administered in an intermittent fashion" but Claim 21 already recites this limitation. Thus, Claim 23 fails to further limit the subject matter of Claim 21.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1632

Claim 5 is indefinite in its recitation of "[hPTH(1-34)]" at the very end of the claim because it is unclear whether the material enclosed in brackets is intended to be included as part of the claim or is intended to be deleted from the claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 15, 16, and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finkelstein et al. (1998).

Finkelstein et al. (1998) disclose a method for preventing bone loss in humans by the subcutaneous administration of parathyroid hormone-(1-34).

Although Finkelstein et al. (1998) disclose administration of the parathyroid hormone fragment by subcutaneous injection, one of skill in the art would have been motivated to consider other modes of administration and would have anticipated a reasonable expectation of success in finding alternate modes of administration as only routine experimentation is required to extend the invention of Finkelstein et al. from the subcutaneous mode of administration to other modes of administration.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Art Unit: 1632

*Conclusion*

Claim 24 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Baker whose telephone number is (703) 306-9155. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached on (703) 305-6608. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

Anne-Marie Baker, Ph.D.

*Anne-Marie Baker*  
ANNE-MARIE BAKER  
PATENT EXAMINER